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09/754,004	01/03/2001	Marc Feldmann	65019-DA-PCT-US/JPW/AJM	2757

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EXAMINER

GAMBEL, PHILLIP

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
1644	9

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Please find below a communication from the EXAMINER in charge of this application

Commissioner of Patents

Applicant's election with traverse of Group I (claims 1-6, 11-19 and 24-38) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the Invention of the Groups I-VIII are not independent since they all relate to methods of treating TNF-mediated disease and the examination of the entire application would not constitute a burden to search.

This is not found persuasive because the inventions are distinct as noted in the previous Restriction Requirement, as shown by the distinctness described therein. Applicant is reminded that MPEP 803 states that the Inventions be either independent or distinct and a burden on the Examiner if restriction is required. Also, applicant's attention is directed to MPEP 806.05 for issues of distinctness.

Regarding applicant's comments about undue burden, the MPEP 803 states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search".

As pointed out previously, prior to setting forth the restriction requirement, it was pointed out that the claims are drawn to patentably distinct methods which rely upon TNF α antagonists that do not comprise a common structural feature that contributes to their common utility and, in turn, rely upon distinct products. The methods rely upon TNF-specific antibodies, p55TNF α receptors, p75TNF α receptors, pentoxifylline, rolipram, thalidomide, tenidap, A2b adenosine receptor agonist and a A2b adenosine receptor enhancer. These TNF α antagonists differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. The examiner notes that these molecules do not share a substantial structural feature essential to a common utility. Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims, because these are not proper species.

Applicant's arguments are not found persuasive because of the reasons of record. The requirement is still deemed proper and is therefore made FINAL.

However, it is noted that applicant's election was not fully responsive the restriction / election of species set forth in the previous Office Action (Paper No. 7). *Applicant should elect a specific disease or disorder (e.g. rheumatoid arthritis) (see pages 6-8 of the instant specification).*

The following is reiterated for applicant's convenience.

This application contains claims directed to the following patentably distinct species of the claimed Groups I- VIII: wherein the TNF-mediate disease is:

- A) an autoimmune disease,
- B) acute or chronic disease,
- C) inflammatory disease, or
- D) neurodegenerative disease.

It is noted that these categories recited in the claims are overlapping. Applicant should elect a specific category of disease (e.g. autoimmune disease or neurodegenerative disease) that would be readily understood by the ordinary artisan (see pages 6-8 of the instant specification)

AND, in addition,

applicant should elect a specific disease or disorder (e.g. rheumatoid arthritis) (see pages 6-8 of the instant specification).

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic, for example.

Also, applicant is reminded that affidavits and declarations, such as those under 37 C.F.R. § 1.131 and 37 C.F.R. § 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit, the applicant should make the remarks of record in the later application and include a copy of the original affidavit filed in the parent application.

Since the above-mentioned amendment appears to be a *bona fide* attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
August 8, 2002